

# EXHIBIT 1

**Issued by the**  
**UNITED STATES DISTRICT COURT**  
**DISTRICT OF NORTH DAKOTA**

BIOVAIL LABORATORIES INTERNATIONAL SRL,  
Plaintiff,

**SUBPOENA IN A CIVIL CASE**

V.

ANDRX PHARMACEUTICALS, LLC, ET AL  
Defendants.

Case Number:<sup>1</sup> C.A. 05-586 (KAJ)  
C.A. 05-730 (KAJ)  
C.A. 06-620 (KAJ)  
(Consolidated)

TO: PRACS INSTITUTE, LTD.  
4801 Amber Valley Parkway  
Fargo, ND 58104

UNITED STATES DISTRICT COURT FOR THE  
DISTRICT OF DELAWARE

YOU ARE COMMANDED to appear in the United States District court at the place, date, and time specified below to testify in the above case.

PLACE OF TESTIMONY	COURTROOM
	DATE AND TIME

YOU ARE COMMANDED to appear at the place, date, and time specified below to testify at the taking of a deposition in the above case. See Attachment B.

PLACE OF DEPOSITION FITZPATRICK, CELLA, HARPER & SCINTO 30 Rockefeller Plaza New York, NY 10112	DATE AND TIME November 29, 2006 9:00 a.m.
--	---

YOU ARE COMMANDED to produce and permit inspection and copying of the following documents or objects at the place, date, and time specified below (list documents or objects): See Attachment A.

PLACE FITZPATRICK, CELLA, HARPER & SCINTO 30 Rockefeller Plaza New York, NY 10112	DATE AND TIME November 16, 2006 9:00 a.m.
--	---

YOU ARE COMMANDED to permit inspection of the following premises at the date and time specified below.

PREMISES	DATE AND TIME

Any organization not a party to this suit that is subpoenaed for the taking of a deposition shall designate one or more officers, directors, or managing agents, or other persons who consent to testify on its behalf, and may set forth, for each person designated, the matters on which the person will testify. Federal Rules of Civil Procedure, 30(b)(6).

ISSUING OFFICER'S SIGNATURE AND TITLE (INDICATE IF ATTORNEY FOR PLAINTIFF OR DEFENDANT)   Dominick A. Conde, Attorney Attorney for Plaintiff	DATE October 17, 2006
---	--------------------------

ISSUING OFFICER'S NAME, ADDRESS AND PHONE NUMBER  
Dominick A. Conde, Fitzpatrick, Cella, Harper & Scinto,  
30 Rockefeller Plaza, New York, NY 10112  
(212) 218-2100

<sup>1</sup> If action is pending in district other than district of issuance, state district under case number.

## PROOF OF SERVICE

SERVED	DATE	PLACE
SERVED ON (PRINT NAME)		MANNER OF SERVICE
SERVED BY (PRINT NAME)		TITLE

## DECLARATION OF SERVER

I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Proof of Service is true and correct.

Executed on \_\_\_\_\_

DATE

SIGNATURE OF SERVER

ADDRESS OF SERVER

**Rule 45, Federal Rules of Civil Procedure, Parts C & D:**

## (c) PROTECTION OF PERSONS SUBJECT TO SUBPOENAS

(1) A party or an attorney responsible for the issuance and service of a subpoena shall take reasonable steps to avoid imposing undue burden or expense on a person subject to that subpoena. The court on behalf of which the subpoena was issued shall enforce this duty and impose upon the party or attorney in breach of this duty an appropriate sanction which may include, but is not limited to, lost earnings and reasonable attorney's fee.

(2) (A) A person commanded to produce and permit inspection and copying of designated books, papers, documents or tangible things, or inspection of premises need not appear in person at the place of production or inspection unless commanded to appear for deposition, hearing or trial

(B) Subject to paragraph (d) (2) of this rule, a person commanded to produce and permit inspection and copying may, within 14 days after service of subpoena or before the time specified for compliance if such time is less than 14 days after service, serve upon the party or attorney designated in the subpoena written objection to inspection or copying of any or all of the designated materials or of the premises. If objection is made, the party serving the subpoena shall not be entitled to inspect and copy materials or inspect the premises except pursuant to an order of the court by which the subpoena was issued. If objection has been made, the party serving the subpoena may, upon notice to the person commanded to produce, move at any time for an order to compel the production. Such an order to comply production shall protect any person who is not a party or an officer of a party from significant expense resulting from the inspection and copying commanded.

(3) (A) On timely motion, the court by which a subpoena was issued shall quash or modify the subpoena if it

- (i) fails to allow reasonable time for compliance,
- (ii) requires a person who is not a party or an officer of a party to travel to a place more than 100 miles from the place where that person resides, is employed or regularly transacts business in person, except that, subject to the provisions of clause (c) (3) (B) (iii) of this rule, such a person may in order to attend

trial be commanded to travel from any such place within the state in which the trial is held, or

(iii) requires disclosure of privileged or other protected matter and no exception or waiver applies, or  
(iv) subjects a person to undue burden.

## (B) If a subpoena

(i) requires disclosure of a trade secret or other confidential research, development, or commercial information, or  
(ii) requires disclosure of an unretained expert's opinion or information not describing specific events or occurrences in dispute and resulting from the expert's study made not at the request of any party, or  
(iii) requires a person who is not a party or an officer of a party to incur substantial expense to travel more than 100 miles to attend trial, the court may, to protect a person subject to or affected by the subpoena, quash or modify the subpoena, or, if the party in whose behalf the subpoena is issued shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship and assures that the person to whom the subpoena is addressed will be reasonably compensated, the court may order appearance or production only upon specified conditions.

## (d) DUTIES IN RESPONDING TO SUBPOENA

(1) A person responding to a subpoena to produce documents shall produce them as they are kept in the usual course of business or shall organize and label them to correspond with the categories in the demand.

(2) When information subject to a subpoena is withheld on a claim that it is privileged or subject to protection as trial preparation materials, the claim shall be made expressly and shall be supported by a description of the nature of the documents, communications, or things not produced that is sufficient to enable the demanding party to contest the claim.

## EXHIBIT A

**ATTACHMENT A**

**DEFINITIONS**

1. The term "thing" means any physical specimen or other tangible item other than a document.
2. The term "document" is used in the broadest sense possible under Rule 34 of the Federal Rules of Civil Procedure, and means any writing or other record whatsoever of every nature, whether transcribed by hand or by some mechanical, electronic, photographic or other means, and regardless of the medium in, or upon which, it is retained or stored, including, without limitation, the following: correspondence; memoranda; electronic mail; notes; records; summaries of meetings or conferences; opinions; studies; reports of consultants; projections; statistical statements; drafts; contracts; agreements; telegrams; telexes; facsimiles; books; pamphlets; manuals; reports; diaries; tape recordings; computer discs; tapes or files; charts; logs; photographs; notebooks; drawings; plans; rules; rulings; regulations; orders; codes; and inter-office communications. "Document" includes every copy of a document that is not identical to the original or any other copy.
3. The term "Biovail" as used hereinafter includes Biovail Laboratories International SRL, its past or present officers, directors, employees, representatives, agents and attorneys, as well as any past or present predecessor, successor, parent, subsidiary, division or affiliate thereof, whether domestic or foreign, whether owned in whole or in part.
4. The term "Andrx" as used hereinafter includes Andrx Pharmaceuticals, LLC, and Andrx Corporation, its past or present officers, directors, employees, representatives, agents and attorneys, as well as any past or present

predecessor, successor, parent, subsidiary, division or affiliate thereof, whether domestic or foreign, whether owned in whole or in part.

5. The terms "you", "your", and "PRACS" shall refer to PRACS Institute, Ltd., its past or present officers, directors, employees, representatives, agents and attorneys, as well as any past or present predecessor, successor, parent, subsidiary, division or affiliate thereof, whether domestic or foreign, whether owned in whole or in part.

6. The term "Andrx's proposed diltiazem hydrochloride product(s)" means Andrx's diltiazem hydrochloride extended release compositions, including those which are the subject of Andrx's Abbreviated New Drug Application No. 77-686, and any other Andrx diltiazem hydrochloride extended release compositions which PRACS, on its own or on its behalf, has tested, evaluated, or otherwise acquired, including but not limited to, Andrx's diltiazem hydrochloride extended release tablets from lot nos. 695P020A, 695P021A, 695R020A, 695P023A, 695P024A, 695R022A, and 695R026A.

7. The singular form of any noun or pronoun used herein includes within its meaning the plural form thereof and vice versa; the neuter, masculine or feminine form of any pronoun used herein includes within its meaning the neuter, masculine and feminine forms; and the use herein of any tense of any verb includes within its meaning all other tenses of the verb. In every such instance, the specific request shall be construed in the broadest sense so as to call for the most complete and inclusive answer.

8. The term "relating to or concerning" means referring to, describing, evidencing or constituting.

9. The conjunctions "and" and "or" shall be individually interpreted in every instance as meaning "and/or" and shall not be interpreted disjunctively to exclude any document or thing otherwise within the scope of any request.

**INSTRUCTIONS**

1. This subpoena for production of documents shall be deemed continuing, requiring you to serve supplemental answers and documents and things promptly in accordance with the Federal Rules of Civil Procedure. Such documents are to be produced as soon as is reasonably possible after they are located or obtained.

2. If you have any good faith objection to any request or any part thereof, the specific nature of the objection and whether it applies to the entire request or to a part of the request shall be stated. If there is an objection to any part of a request, then the part objected to should be identified and documents responsive to the remaining unobjectionable part should be produced.

3. Each request shall be answered separately, and you shall indicate for each document the request to which it responds.

4. Each request shall be answered on the basis of your entire knowledge, from all sources, after an appropriate and good faith inquiry has been made and a search has been conducted.

5. For each document and thing requested herein that you withhold or redact under a claim of attorney-client privilege, work product immunity, or any other privilege or immunity, you shall provide at the time of production an explanation of the basis for the claim, including:

- a. the date of the document;
- b. the type of document (e.g., letter, memorandum, etc.);

- c. the name and title of any and all authors or senders and any and all addressees and copy recipients of the document and any and all persons to whom the document was shown or to whom its subject matter was disclosed;
- d. the name of each person or persons (other than stenographic or clerical assistants) participating in the preparation of the document or in whose name the document was prepared;
- e. the subject matter of the document;
- f. the document request to which the document is responsive; and
- g. a statement of the basis upon which the document has been redacted or withheld, including the specific nature of the privilege or exemption claimed and the detailed grounds for claiming such.

6. For any document requested herein that has been destroyed or misplaced, you shall provide the information described in paragraphs 5(a.)-(e.) above, as well as a brief explanation of the circumstances (*e.g.*, when, how, by whom, and why) surrounding the document's destruction or loss, and any and all records pertaining to its destruction or loss.

7. If you or your attorneys know of the existence, past or present, of any document described in a request, but such document is not presently in your possession, custody, or control or in the possession, custody, or control of its agents, representatives, or attorneys, you shall so state in response to the request, identify such

document in response to the request, and identify the individual in whose possession, custody, or control the document was last known to reside.

8. If documents are produced as they are maintained in the normal course of business:

- a. all associated file labels, file headings, and file folders shall be produced together with the responsive documents from each file, and each file shall be identified as to its owner or custodian;
- b. all documents that cannot be legibly copied shall be produced in their original form; otherwise, defendants may produce photocopies; and
- c. each page shall be given a discrete production number.

### **REQUESTS FOR THE PRODUCTION OF DOCUMENTS**

#### **Request No. 1**

All documents and things relating to or concerning Andrx's proposed diltiazem hydrochloride product(s).

#### **Request No. 2**

All documents and things, including but not limited to, notebooks, meeting minutes, analyses, and reports, relating to or concerning the formula, chemical composition, and physical characteristics of Andrx's proposed diltiazem hydrochloride product(s).

Request No. 3

All documents and things, including but not limited to, notebooks, meeting minutes, analyses, and reports, relating to or concerning any testing, evaluation or experimentation relating to Andrx's proposed diltiazem hydrochloride product(s) done by or on behalf of PRACS or Andrx.

Request No. 4

All documents and things, including but not limited to, notebooks, meeting minutes, analyses, and reports, relating to or concerning all protocols, experiments, tests, evaluations, and data relating to Andrx's proposed diltiazem hydrochloride product(s) that were considered, attempted, done, or are to be done, by or on behalf of PRACS or Andrx, or anyone acting on Andrx's behalf (including its consultants, experts and counsel).

Request No. 5

All documents and things, including but not limited to, notebooks, meeting minutes, analyses, and reports, relating to or concerning bioavailability, bioequivalence, or pharmacokinetic studies performed using Andrx's proposed diltiazem hydrochloride product(s) done by or on behalf of PRACS or Andrx.

Request No. 6

All documents and things relating to or concerning any communications between PRACS and any other entity relating to Andrx's proposed diltiazem hydrochloride product(s).

Request No. 7

All documents and things, including but not limited to, notebooks, meeting minutes, analyses, and reports, relating to or concerning the dissolution, bioavailability, stability or degradation of Andrx's proposed diltiazem hydrochloride product(s).

Request No. 8

All documents and things, including but not limited to, notebooks, meeting minutes, analyses, and reports, relating to or concerning dissolution testing of Andrx's proposed diltiazem hydrochloride product(s) in either water or in a buffered medium having a pH between about 5.5 and about 6.5.

Request No. 9

All documents and things relating to or concerning Cardizem® LA diltiazem hydrochloride tablets.

Request No. 10

All documents and things relating to or concerning any attempts to copy, reverse engineer or otherwise test, analyze or study Cardizem® LA diltiazem hydrochloride tablets.

Request No. 11

All documents and things, including but not limited to, notebooks, meeting minutes, analyses, and reports, relating to or concerning all protocols, experiments, tests, evaluations, and data relating to Cardizem® LA diltiazem hydrochloride tablets that were considered, attempted, done, or are to be done, by or on

behalf of PRACS or Andrx, or anyone acting on Andrx's behalf (including its consultants, experts and counsel).

Request No. 12

All documents and things, including but not limited to, notebooks, meeting minutes, analyses, and reports, relating to or concerning bioavailability, bioequivalence, or pharmacokinetic studies performed with Cardizem® LA diltiazem hydrochloride tablets done by or on behalf of PRACS or Andrx.

Request No. 13

All documents and things, including but not limited to, notebooks, meeting minutes, analyses, and reports, relating to or concerning the dissolution, bioavailability, stability or degradation of Cardizem® LA diltiazem hydrochloride tablets.

Request No. 14

All documents and things relating to or concerning any comparison between Cardizem® LA diltiazem hydrochloride tablets and Andrx's proposed diltiazem hydrochloride product(s).

Request No. 15

All documents and things relating to or concerning any opinions or statements regarding the bioequivalence, or lack thereof, between Cardizem® LA diltiazem hydrochloride tablets and Andrx's proposed diltiazem hydrochloride product(s).

Request No. 16

All document and things relating to or concerning Cmax determinations of Andrx's proposed diltiazem hydrochloride product(s).

Request No. 17

All document and things relating to or concerning protocols regarding the determination of Cmax for Andrx's proposed diltiazem hydrochloride product(s).

Request No. 18

All document and things relating to or concerning determinations of bioavailability of Andrx's proposed diltiazem hydrochloride product(s) when given at night compared to when given in the morning without food.

Request No. 19

All document and things relating to or concerning bioequivalence determinations of Andrx's proposed diltiazem hydrochloride product(s) in the morning with and without food.

## EXHIBIT B

**ATTACHMENT B**

**SUBJECTS FOR EXAMINATION**

1. Protocols, experiments, tests, evaluations, and data relating to or concerning Andrx's proposed diltiazem hydrochloride product(s), including but not limited to those that were considered, attempted, prepared or completed by PRACS, Andrx, or anyone acting on Andrx's behalf (including its consultants, experts and counsel).

2. Protocols, experiments, tests, evaluations, and data relating to or concerning Cardizem® LA diltiazem hydrochloride tablets, including but not limited to those that were considered, attempted, prepared or completed by PRACS, Andrx, or anyone acting on Andrx's behalf (including its consultants, experts and counsel).

3. Bioavailability, bioequivalence, and pharmacokinetic studies or trials performed by or on behalf of PRACS or Andrx relating to or concerning Andrx's proposed diltiazem hydrochloride product(s), including but not limited to data, analyses and results of those studies or trials.

4. Bioavailability, bioequivalence, and pharmacokinetic studies or trials performed by or on behalf of PRACS or Andrx relating to or concerning Cardizem® LA diltiazem hydrochloride tablets, including but not limited to data, analyses and results of those studies or trials.

5. Analytical testing performed by or on behalf of PRACS or Andrx relating to or concerning Andrx's proposed diltiazem hydrochloride product(s) or Cardizem® LA diltiazem hydrochloride tablets, including but not limited to data, analyses and results of that testing.

6. Opinions, conclusions, or statements relating to or concerning the bioequivalence, or lack thereof, between Cardizem® LA diltiazem hydrochloride tablets and Andrx's proposed diltiazem hydrochloride product(s).

7. Protocols, experiments, tests, evaluations, and data relating to or concerning determinations of Cmax for Andrx's proposed diltiazem hydrochloride product(s).

8. Bioavailability, bioequivalence, and pharmacokinetic studies or trials performed by or on behalf of PRACS or Andrx relating to or concerning the bioavailability of Andrx's proposed diltiazem hydrochloride product(s) when given at night compared to when given in the morning without food.

9. Bioavailability, bioequivalence, and pharmacokinetic studies or trials performed by or on behalf of PRACS or Andrx relating to or concerning the bioequivalence of Andrx's proposed diltiazem hydrochloride product(s) in the morning with and without food.

10. Communications between PRACS and Andrx regarding items 1 – 9 above.

11. The review and collection of documents requested in Attachment A, including but not limited to, all steps taken to identify responsive documents, what files were searched for those documents, and what individuals were questioned as to whether they had responsive documents.

**CERTIFICATE OF SERVICE**

I, the undersigned, hereby certify that on October 17, 2006, I caused to be electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following:

Richard L. Horwitz  
Potter Anderson & Corroon LLP

and that I caused copies to be served upon the following in the manner indicated:

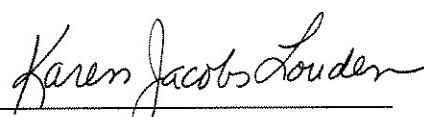
**BY HAND**

Richard L. Horwitz  
Potter Anderson & Corroon LLP  
Hercules Plaza, 6th Floor  
1313 North Market Street  
Wilmington, DE 19899

**BY FEDERAL EXPRESS**

Martin P. Endres  
Hedman & Costigan, P.C.  
1185 Avenue of the Americas  
New York, NY 10036

Steven Maddox  
Foley & Lardner, LLP  
3000 K Street, NW  
Washington, DC 20007

/s/   
\_\_\_\_\_  
klouden@mnat.com